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EXAMINER	
MARX, IRENE	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/438,872
Filing Date: November 12, 1999
Appellant(s): COCHRUM ET AL.

Eugene Rzucidlo
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/6/04.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: The 35 U.S.C § 103 rejection is over GB '055 in view of Larson or Eloy *et al.* and Nangia *et al.* (not "Wang").

(7) Grouping of Claims

The rejection of claims 1, 3, 9, and 11 through 13 stands or falls together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

GB 454055	Pharmacia Aktiebolag	10-1976
5196190	NANGIA ET AL.	03-1993

Larson, "Topical hemostatic agents for dermatologic surgery", J. Dermatol. Surg. Oncol. 14 (6) : 623-32 (1988).

Eloy et al., "An in vitro evaluation of the hemostatic activity of topical agents", J. Biomed. Mater. Res. 22 (2) :149-57 (1988).

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

a) The rejection of claims 1, 3, 9, 12 and 13 under 35 U.S.C § 102.

Claims 1, 3, 9, 12 and 13 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by G.B. 1454055 [N].

The claims are directed to a dry, stable, sterile wound dressing comprising a matrix containing a hemostatic polymer of cross-linked dextran which has a molecular weight exclusion limit of 100,000 to 650,000, and having certain functional properties such as triggering release of clotting factors and other ancillary substances .

G.B. 1454055 discloses a wound dressing comprising dextran-epichlorohydrin polymer particles or beads wherein in at least one embodiment the hydrophilic polymer is chosen such that its pores will exclude "high molecular weight degradation products of the fibrinogen, for example such as those degradation products having a molecular weight of between about 270,000 and 165,000." (See, e.g., page 2, lines 3-9). This molecular weight falls within the range claimed. The GB '055 specifically notes the inclusion of the "so-called thrombocyte factors which influence the first phase of the blood coagulation process" in the wound dressing (See, e.g., page 1, col. 2, line 91). The matrix disclosed may be paper, cotton fabric, inert plastics, etc. (page 6). Disinfectants may be added to the carrier (page 6, line 36). Sterilization may be by gamma irradiation (page 6, line 130).

With respect to the added limitation regarding the property of the cross-linked dextran of triggering release of "clotting factors and other ancillary substances", this function is an inherent property of cross-linked dextrans.

b) The rejection of claim 11 under 35 U.S.C § 103.

Claim 11 stands rejected under 35 U.S.C. 103(a) as being unpatentable over G.B. 1454055 [N] as applied to claims 1, 3, 9, 12 and 13 above, and further in view of Larson or Eloy *et al.* and Nangia *et al.* (US 5,196,190 [B], incorrectly indicated as "Wang").

The claim is directed to a dry, stable, sterile wound dressing comprising a matrix containing a hemostatic polymer of cross-linked dextran which has a molecular weight exclusion limit of 100,000 to 650,000, having certain functional properties such as triggering release of clotting factors and containing collagen or thrombin or fibrinogen.

Collagen, fibrinogen or thrombin are known hemostatic agents as described by Larson [R] or Eloy *et al.* [S]

US 5,196,190 teaches that cross-linked dextran has hemostatic properties (col. 10, line 50).

The addition of thrombin or fibrinogen or collagen to the wound dressing of G.B. 1,454,055 would have been obvious when the reference was taken with Larson or Eloy *et al.* and '190 because cross-linked dextran, thrombin, fibrinogen and collagen are known hemostatic agents and have been used in the past as such.

It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

(11) Response to Argument

a) The rejection of claims 1, 3, 9, 12 and 13 under 35 U.S.C § 102.

In response to the rejection, Appellant argues that the GB '055 fails to teach to suggest a hemostatic polymer composition which is useful for the rapid induction of blood coagulation and hemostasis at a bleeding site, because this is not an intended use of the invention claimed in GB '055.

However, Appellant fails to appreciate that the rejected claims are drawn to composition and not to a process of using the composition for the rapid induction of blood coagulation and hemostasis at a bleeding site as alleged.

Appellant also indicates that a feature of the hemostatic agent and polymer composition of the present invention is that dextran concentrates fibrinogen on the surface of the beads which in turn triggers rapid blood clotting and hemostasis directly at the active bleeding site, where such materials remain. Appellant alleges that the instant claims are limited in a way such that cross-linked dextran beads which do not induce clotting at a bleeding are excluded from the claims (Brief, page 6, paragraph 6). It is respectfully submitted that the functional limitations fail to limit the instant claims drawn to a composition having a specific structure. Any functions of the composition are inherent in the structural elements recited. A careful comparison of the structural elements of the invention as claimed and the structural elements recited in the reference demonstrates that the structural elements are the same.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established.

Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure being claimed, the properties Applicant discloses and/or claims are necessarily present. It is immaterial what the properties of the composition are or who discovered the properties because the composition is the same and thus must necessarily exhibit the properties. MPEP 2112.01

Inasmuch as the claims are directed to a composition, any differences in alleged effects are due to the length of exposure of the composition to a wound in a method of using the composition. In the British patent, the dry, stable, sterile wound dressing comprising a matrix containing a hemostatic polymer of cross-linked dextran which has a molecular weight exclusion limit of 100,000 to 650,000 is intended to be used primarily for the prevention of the formation of scars in wounds, while in the instant case, the same composition is intended to be used to control active bleeding at a wound by rapid blood coagulation. The type of wound encountered

and the time of application are seen to affect the effects obtained by applying the same matrix of cross-linked dextran which has a molecular weight exclusion limit within the claimed exclusion limit of 100,000 to 650,000. In the instant case, the touted advantages of the claimed composition have not been correlated to specific differences in the structural elements of the compositions compared. In other words, Appellant has not demonstrated unexpected properties of the claimed composition over the composition of the '055 reference in a side-by-side comparison, for example.

It is noted that Appellant admits on the record that the British patent and the present application are both directed to dextran-epichlorohydrin polymers (Brief, page 6, lines 8-9). The Examiner disagrees with the Appellant's interpretation of the reference regarding "consistency of the polymer in the patent GB '055", since Appellant contends that the consistency "is such that high molecular weight (e.g., MW 50000-270000 degradation products of fibrinogen) are partly or completely excluded from the gel particles of that polymer". Appellant fails to indicate which portion of the patent is being cited. If Appellant refers to col. 2, lines 4 et seq., it is the Examiner's position that this portion of the reference indicates that the preferred range in one embodiment is not from 50,000 to 270,000 as alleged, but that the embodiment encompasses a preferred molecular exclusion of 165,000, and goes up to 270,000, since it states "[I]n accordance with one embodiment of the invention the macromolecular material may be such that high molecular weight degradation products of the fibrinogen, for example those having a molecular weight of over 270,000, preferably over 165,000 ... are completely or partially excluded from the particles". The material omitted refers to other "possible" examples of molecular weights excluded.

Appellants arguments directed to differences in the "intended use of the compositions" (Brief, page 6, paragraph 3) fail to persuade since a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In order to be limiting, the intended use must create a structural difference

between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus, the intended use is not limiting. "The claiming of a new use . . . which is inherently present in the prior art does not necessarily make the claim patentable." *In re Best*, 195 USPQ 430, 433 (CCPA 1977). (MPEP 2112).

b) The rejection of claim 11 under 35 U.S.C § 103.

Appellants argue that there is no suggestion in any of the references to combine their disclosures in a manner that would disclose the compositions or methods of use of the compositions claimed. To begin with, it is noted with all due respect that the claims on appeal are all composition claims. In addition, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 19880; In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Eloy and Larson teach that at least collagen and fibrin are involved in hemostasis and would naturally accelerate wound healing. See, Eloy, pages 155-156 and Larson, pages 626 and 627. In addition Larson specifically uses fibrin as a sealant or tissue glue.. Moreover, US '190 (Nangia) demonstrates that crosslinked dextran similarly is suitable as a hemostatic agent and wound healing promoter. See, e.g., Col. 10, Results.

Contrary to appellant's arguments, the various references in combination clearly disclosed to one of ordinary skill in the art at the time the claimed invention was made that agents such as crosslinked dextran collagen and fibrin are all suitable for the same purposes of treating surface wounds for the purpose of encouraging prompt hemostasis and healing.

Therefore, one of ordinary skill in the art would have had a compelling motivation to combine the hemostatic composition of GB '055 containing crosslinked dextran with agents such as collagen and fibrin as taught by Eloy, Larson and '190, given that crosslinked dextran, collagen and fibrin are all agents recognized in this art as suitable to treat and protect wounds and promote hemostasis, in order to obtain a composition that maximizes hemostasis and/or healing of wounds, which are a serious problem in war and accidents.

Appellant has not demonstrated with **objective evidence** any unexpected properties of the claimed composition over the reference composition. The arguments by counsel in this regard have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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February 8, 2005

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